

REMARKS

In the Non-Final Office Action mailed February 8, 2008, claims 39-53, 57, 60, 74-76 and 87-94 were pending. Each of claims 39-53, 57, 60, 74-76 and 87-94 currently stands rejected. In view of the following remarks, reconsideration and allowance of the present application including claims 39-53, 57, 60, 74-76 and 87-94, are hereby requested. Of the pending claims, claim 39 is the only independent claim

As an initial matter, Applicant filed a Supplemental Response in the present application with the Patent Office on January 30, 2008. In a follow-up telephone conversation with Examiner Carter on February 1, 2008, Applicant discovered that the contents of the Supplemental Response were not considered before the outstanding Office Action was prepared. To that end, consideration of the aforementioned Supplemental Response along with this Response is respectfully requested. The Supplemental Response provided information and exhibits which Applicant believes qualify as objective indicia of non-obviousness of the subject matter claimed in the present application.

Applicant acknowledges and thanks the Examiner for the indication in the outstanding Action that the previously-asserted rejection of claims 39, 49, 57, 74, 76 and 88 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,079,299 to Heilig (hereafter "Heilig") is withdrawn. However, claims 39, 49, 57, 74, 76 and 88 now stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig; claims 40-53 and 60 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 6,217,890 to Paul et al. (hereafter "Paul") and in further view of U.S. Patent No. 6,103,245 to Clark et al. (hereafter "Clark"); claims 51 and 52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 5,330,756 to Stuart et al. (hereafter "Stuart"); claims 74, 75, 87, 89, 93 and 94 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 5,881,925 to Ando (hereafter "Ando"); claims 90 and 91 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No. 5,169,037 to Davies et al. (hereafter "Davies"); and claims 90 and 92 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Heilig in view of U.S. Patent No.

5,249,747 to Hanson et al. (hereafter “Hanson”). For at least the reasons that follow, Applicant submits that each of claims 39-53, 57, 60, 74-76 and 87-94 is patentable over the cited references. Of the pending claims, the only independent claim is claim 39, which is rejected as being unpatentable over Heilig alone.

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. See, Manual of Patent Examining Procedure (MPEP) §2141. From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness. For at least the reasons discussed hereinbelow, it is respectfully submitted that a *prima facie* case of obviousness has not been established in this case.

In addition to the above, in order for an obviousness rejection to be proper, the prior art reference, or references when combined, must teach or suggest all the claim limitations. See, MPEP §2142 (citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Independent claim 39 recites, in combination with other features and elements, “. . . passing the composition through the mechanism . . . to provide a moisture barrier over the skin treatment area . . .” Applicant submits that Heilig does not teach or suggest this claim limitation. The Office Action asserts that Heilig, at column 2, lines 7-11, discloses a moisture barrier as set forth in claim 39. This portion of Heilig recites:

[w]hen the aerosol ointment composition is atomized onto the affected area of the body, the polyethylene resin provides a breathing film which permits access of air and oxygen to the affected area of the body and facilitates the rapid release of the medicament to the affected area, thereby accelerating the healing of infections, burns and other wounds.

The suggestion that this portion of Heilig discloses a moisture barrier is respectfully traversed. Indeed, the above language from Heilig does not provide any discussion related to a moisture barrier.

As a further matter, the remaining portions of Heilig are also silent with respect to a composition that forms a moisture barrier. In fact, Heilig is directed to compositions that are permeable and exhibit superior breathing characteristics which, in at least one example, permit the passage of fluids and vapors through them. See e.g., column 6, lines 52-58. One specifically disclosed example of a fluid that passes through the composition is serum. As would be appreciated by one skilled in the art, the term “serum” generally refers to any watery fluid of an animal. To that end, a composition that permits serum to pass through it clearly fails to provide a moisture barrier over the skin. Furthermore, those skilled in the art would not modify Heilig to arrive at a composition that provides a moisture barrier over the skin. Heilig discloses that the aforementioned permeability is beneficial because it prevents serum collection between the skin and the composition which eliminates a culture for bacterial and fungal growths. See e.g., column 6, lines 56-58. When considering this benefit, as well as the many other advantages Heilig attributes to its permeable and breathable compositions, one skilled in the art would not modify Heilig to arrive at a composition which provides a moisture barrier over a skin treatment area, as recited in independent claim 39 because such a modification would render the composition unsatisfactory for its intended purpose, namely, the purpose of providing a water permeable layer. Accordingly, for at least these reasons, a *prima facie* case of obviousness of claim 39 in view of Heilig has not been established. If the assertion that Heilig discloses this feature is maintained, Applicant respectfully requests specific citation to the portion(s) of Heilig which discloses a moisture barrier or, alternatively, an explanation how a water permeable layer can operate as a moisture barrier.

Independent claim 39 also recites, in combination with other features and elements, “. . . wherein the dispenser is not an aerosol device” As Applicant previously submitted, Heilig only discloses the use of an aerosol device. See e.g., *Response to Final Office Action* filed October 31, 2007. The Office Action now acknowledges that Heilig fails to teach any dispenser other than an aerosol device. See

e.g., Office Action, page 5. However, the Office Action indicates at page 5 that it would have been obvious to modify Heilig to utilize a dispenser that is not an aerosol device because:

[t]he Heilig [sic] teaches that the primary objective of the invention is to provide a self-propelling fluid medicinal ointment composition adapted to be atomized from a fluid-tight container and which when applied directly as a fine spray or mist to the body to be treated provides a breathing covering of polyethylene filament from which the medicament is rapidly released to the treated area of the body.

The Office Action also indicates, on page 6, that despite Heilig's focus on aerosol devices, "one skilled in the art is aware of other atomizing devices that provide the same effect of providing a fine spray or mist." As will be discussed further below, however, Heilig teaches away from a modification which utilizes a dispenser other than an aerosol device. Moreover, the teachings of Heilig do not support the substitution of other atomizing devices for its aerosol delivery mechanism as suggested by the Office Action.

Applicant respectfully submits that the portions of Heilig teaching away from using a dispenser that is not an aerosol device have not been given proper consideration in the instant obviousness analysis. It is well established that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP §2141.02 (citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). When the teachings of Heilig are taken as a whole, it is clear that it discourages the delivery of the composition through any means other than the aerosol form. In fact, as will be established below, not only is the use of an aerosol spray the only delivery mechanism disclosed in Heilig, the use of propellant gases in an aerosol delivery mechanism is critical and necessary to achieve the objects set forth by Heilig.

One of the primary objects of Heilig is to provide a self-propelling fluid. Applicant submits that providing a "self-propelling" fluid necessarily means providing an aerosol fluid. Indeed, Applicant's position is supported by the full disclosure of Heilig, in that the only type of self-propelling fluid it discloses is an aerosol. More specifically,

Heilig provides several examples of “self propelling ointment compositions according to the invention.” See, column 3, lines 6-8. In each of the examples, the “self-propelling” ointment compositions include very high percentages of inert volatile propellant. No references have been cited that provide self-propelling fluids that are not aerosol fluids. As a corollary, Applicant submits that providing the Heilig compositions in anything other than an aerosol form would undermine one of Heilig’s primary objectives; i.e., the compositions would not be self-propelling.

Another primary object of Heilig is “to provide a breathing covering of polyethylene filaments from which the medicant is rapidly released to the treated area of the body.” See, column 1, lines 34-37. As would be appreciated by those skilled in the art, porosity and breathability of a skin coating are particularly important when treating a skin lesion or burn, with treatment of both being emphasized in Heilig. Moreover, Heilig clearly establishes that the breathability of its compositions is achieved through a physical interaction between the aerosol propellant and the polyethylene filaments. For example, Heilig discloses at column 2, lines 13-19:

The propelling of the ointment with a liquefied gaseous propellant cooperates with the structural characteristics of the polyethylene in such a way that the filaments of the polyethylene resin are interlaced in a loose dispersion over the affected area of the body to provide a breathing covering permitting the access of air and oxygen and the rapid release of the medicant to the affected area.

As a further example, Heilig discloses at column 7, line 73 to column 8, line 4:

The polyethylene and propellant in the composition cooperate in such a way that the polyethylene filaments are interlaced in a loose dispersion over any burned or affected area when sprayed by the propellant. A much more porous and spongy structure is produced as a result of the propellant gas leaving the sprayed particles of the base, which occurs almost instantly.

As yet another example, Heilig discloses at column 9, lines 7-15:

Furthermore, the mixture of the propellant gases permits the application of the correct amount of ointment in a manner such that the effective ingredients of the ointment

are held on the affected area of the skin by a lattice of polyethylene filaments which are loosely interlaced over each other as they are propelled onto the affected area by the propellant, thereby providing a breathing film which permits access of air to and accelerates the release of the medicant to the affected area.

As a further matter, Heilig discloses that the aerosol sprayed ointment provides “superior breathing characteristics.” See, column 6, lines 70-71. Moreover, one of the listed advantages from the application of the aerosol mixture is that it “. . . permits the passage of fluid and vapors through it . . .” thereby preventing the collection of serum which eliminates a culture for bacterial and fungal growths. See, column 6, lines 52-58. In view of the foregoing, it is clear Heilig teaches that providing its compositions in anything other than an aerosol form would undermine another one of its primary objectives i.e., the compositions would no longer have a loose dispersion over the skin and would fail to include enhanced breathing characteristics.

Heilig is also replete with indications of other general advantages provided by using an aerosol delivery mechanism. For example, it discloses that the “properties of the polyethylene base employed in the composition of the present invention are greatly enhanced and other advantageous properties obtained when the base is incorporated as an ingredient in an aerosol medicinal ointment composition . . .” See, column 2, lines 1-5. In still another example, Heilig discloses that previous ointments containing polyethylene did not achieve “the outstanding results which have been obtained by utilizing the polyethylene base and medicament in an aerosol.” See, column 2, lines 20-24. In yet another example, Heilig discloses “[w]hen neomycin undecylenate is combined with the polyethylene ointment base in an aerosol composition, it has been found to be unusually effective . . .” See, column 3, lines 2-4. As a further example, Heilig discloses that “[t]he aerosol compositions of all the examples have been used effectively in the treatment of burns and other wounds.” See, column 5, lines 20-22. As an even further example, it is disclosed that the aerosol composition of example 6 was used on skin lesions with excellent results. See, column 5, lines 35-41. It is also disclosed that the aerosol composition of example 6 “provided a superior method for

the treatment of lesions of the skin where the continuity of the skin is disturbed.” See, column 5, lines 53-55. In yet a further example, with respect to the composition of example 7, Heilig discloses that “unusual and unexpected results were obtained with a first-aid aerosol spray . . . in the treatment of burns and other conditions.” See, column 5, lines 56-60. In addition to these examples, Heilig also provides (beginning at column 6, line 32) four specific advantages from the application of the aerosol mixture. These examples clearly impress upon those of skill in the art the reliance of Heilig on an aerosol delivery mechanism to achieve its advantageous effect, thereby discouraging departure from its aerosol delivery mechanism.

As a further matter, modifying Heilig to include a non-aerosol device would also render it unsuitable for its intended purpose. Particularly, Heilig involves a highly viscous ointment that can only be delivered as described therein if it is first dispersed in a very large amount of “inert volatile propellant” under high pressures to enable it to be delivered via an aerosol mechanism. Considering Examples 1 through 8 set forth in Heilig at Columns 3-5, it is seen that each formulation includes at least 70% inert volatile propellant by weight, and some of the preferred formulations include much higher proportions of inert volatile propellant, up to more than 95% by weight. Absent this aerosol mechanism, which relies on very high proportions of volatile propellants, the “ointment base” described in Heilig could not be sprayed, and would therefore be unsatisfactory for its intended use.

In view of the foregoing, Applicant respectfully submits that Heilig clearly teaches away from utilizing a dispenser that is not an aerosol device, as recited in claim 39. As a corollary, those skilled in the art would be dissuaded from modifying Heilig as suggested in the Office Action.

As a further matter, the teachings of Heilig are not broad enough to suggest the substitution of other known atomizing devices for its aerosol delivery mechanism, as suggested by the Office Action. As indicated above, every embodiment of Heilig, and the advantageous results associated therewith, is dependent on an aerosol delivery device. As a corollary, the conclusion that any other atomizing device could be used is overly presumptuous. More particularly, while other atomizing devices may work to provide a fine spray or mist of some compositions, such devices must also be capable of working

with the compositions disclosed by Heilig. The outstanding Office Action has not provided any explanation, or cited any references, which support the operability of these other atomizing devices with the compositions of Heilig. Moreover, given the elaborate discussion and examples in Heilig of its reliance on the aerosol mechanism for both the delivery and beneficial results of the compositions, one skilled in the art would not have contemplated that other atomizing devices could be used to provide the same results as those that are achieved through the use of Heilig's aerosol delivery mechanism. Accordingly, modifying Heilig to use a dispenser that is not an aerosol device would not have been obvious to those skilled in the art.

The Office Action also cites In re Leshin, 277 F. 2d 197, 125 U.S.P.Q. 416 (CCPA 1960) as supporting the obviousness rejection of claim 39 and asserts that no unexpected results have been provided regarding the use of a non-aerosol device. See, Office Action, pages 6 and 19. Applicant respectfully submits that In re Leshin is distinguishable from the present application. In In re Leshin, the claimed subject matter was directed to, *inter alia*, a container formed of a particular type of molded plastic. The prior art at issue showed a substantially similar container formed of a different type of molded plastic. In an attempt to overcome an obviousness rejection, the applicant argued that even though the use of plastics in this manner was well known, the type of plastic he used had been selected for his particular purpose. See, In re Leshin, page 418. In response, the Court held that merely selecting one type of plastic from a group of known plastics to form a container that had already been formed of plastic would be obvious. See, Id. at page 419.

In re Leshin is distinguishable from the present case at least because in the instant case Heilig teaches away from selecting any type of atomizing device other than an aerosol delivery mechanism. In contrast, In re Leshin does not suggest that the prior art at issue taught away from selecting the type of plastic chosen by the applicant. Moreover, In re Leshin dealt with the selection of one type of material that would clearly yield the same results as other types of materials that had already been used in the same manner. In the present application, given Heilig's extensive discussion on the significance of the aerosol delivery mechanism, and the complex rheological characteristics of its compositions, those skilled in the art would not have expected that

modifying Heilig to include a non-aerosol delivery mechanism would provide the same results. Therefore, In re Leshin is distinguishable for this reason as well.

As a further matter, Applicant respectfully traverses the assertion that no unexpected results have been provided regarding the use of a non-aerosol delivery mechanism. Indeed, when considering the contents of the prior art, the successful application of the composition set forth in claim 39 with a dispenser that is not an aerosol device is itself an unexpected result. The subject matter of the pending claims of the present application is directed to unique compositions that include a solid particulate material, and that have a specified combination of physical properties whereby, upon application of a coating of the composition to a skin treatment area, the coating “does not run off the skin treatment area.” The cited references do not describe any compositions that meet the recited properties of sprayability and run-off resistance, that include solid particulate material and that are delivered using a non-aerosol spray delivery mechanism, as recited in the pending claims. In fact, in view of Heilig’s disclosure, those skilled in the art would not expect that the Heilig compositions could be successfully applied without a large amount of aerosol propellant entrained therein. Thus, successfully applying the composition set forth in claim 39 without an aerosol propellant entrained therein (i.e., with a dispenser that is not an aerosol device), provides a result that is unexpected over the prior art. For additional discussion and evidence of this unexpected result, Applicant directs further attention to the Harper and Shah Declarations filed May 26, 2006.

In view of the foregoing, Applicant respectfully requests withdrawal of this rejection and allowance of claim 39. Each of claims 49, 57, 74, 76 and 88 depends from claim 39 and is submitted as patentable for at least the reasons supporting the patentability of claim 39.

As indicated above, pending claims 40-53, 60, 74, 75, 87 and 89-94 stand rejected as being unpatentable under 35 U.S.C. §103(a) over various combinations of references. Applicant initially points out that each of the claims rejected under 35 U.S.C. §103(a) depends, directly or indirectly, from independent claim 39. For the reasons set forth above, the only ground for rejecting claim 39 set forth in the Action has been overcome and claim 39 is in condition for allowance. It is axiomatic that all dependent claims depending from


an allowable base claim are also allowable for at least the same reasons that the independent claim is allowable. As such, Applicant submits that the rejections of dependent claims 40-53, 60, 74, 75, 87 and 89-94 cannot be sustained for at least this reason. Applicant also refers to the *Response to Final Office Action* filed October 31, 2007 for providing additional reasons supporting the patentability of these claims.

Closing

In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, including claims 39-53, 57, 60, 74-76 and 87-94, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

By: _____


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